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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/683,880	10/09/2003	Kun Ping Lu	BIZ-045CPCN	7888

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LAHIVE & COCKFIELD
28 STATE STREET
BOSTON, MA 02109

EXAMINER	
YAEN, CHRISTOPHER H	

ART UNIT	PAPER NUMBER
1643	

DATE MAILED: 04/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/683,880	LU ET AL.	
	Examiner	Art Unit	
	Christopher H. Yaen	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 May 2005*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,10,11,16,28-30,37-41,46 and 56-61* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1,2,10,11,16,28-30,37-41,46 and 56-61* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

RE: Lu et al

Election/Restrictions

6. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1,2,10-11,16, 28-30, and 46 drawn in part to a method of detecting abnormal cell growth and determining a stage of abnormal cell growth comprising the assessment of Pin 1 levels in a sample, wherein the Pin 1 levels are drawn solely to protein, classified in class 435, subclass 7.1, for example.

II. Claims 1,10,28, and 29 drawn in part to a methods of detecting abnormal cell growth and determining a stage of abnormal cell growth comprising the assessment of Pin 1 levels in a sample, wherein the Pin1 levels are drawn solely to nucleic acid levels, classified in class 435, subclass 6, for example.

III. Claims 37 and 38, drawn in part to a method of evaluating the efficacy of treatment of abnormal cell growth comprising comparing the levels of Pin 1 in at least two test samples, wherein a decrease in the Pin 1 levels as compared to controls is indicative of effective treatment, wherein the Pin 1 levels are drawn solely to Pin 1 proteins levels, classified in class 435, subclass 7.21, for example.

IV. Claim 37, drawn in part to a method of evaluating the efficacy of treatment of abnormal cell growth comprising comparing the levels of Pin 1 in at

least two test samples, wherein a decrease in the Pin 1 levels as compared to controls is indicative of effective treatment, wherein the Pin 1 levels are drawn solely to Pin 1 nucleic acid levels, classified in class 435, subclass 5, for example.

V. Claims 39-41, drawn in part to a kit comprising one or more reagents for detecting Pin 1 protein levels, classified in class 530, subclass 387.1, for example.

VI. Claims 39-41, drawn in part to a kit comprising one or more reagents for detecting Pin 1 nucleic acid levels, classified in class 536, subclass 24.31, for example.

VII. Claims 56-61, drawn in part to a method of treating a subject comprising the administration of a Pin1 modulator, wherein the modulator specifically modulates the protein, classified in class 424, subclass 130.1, for example.

VIII. Claims 56-61, drawn in part to a method of treating a subject comprising the administration of a Pin1 modulator, wherein the modulator specifically modulates the nucleic acid, classified in class 514, subclass 44, for example.

7. The inventions are distinct, each from the other because of the following reasons:

8. Inventions I-IV and VII-VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant

case, the instant specification does not disclose that these methods would be used together. The method of detecting, evaluating or treating using a Pin 1 protein antibody (groups I, III, and VII), and the method of detecting, evaluating, or treating using a Pin 1 nucleic acid (group II, IV, and VIII) are all unrelated as they comprise distinct steps and utilize different products which demonstrates that each method has a different mode of operation. Each invention performs this function using a structurally and functionally divergent material (i.e. protein and nucleic acid). Moreover, the methodology and materials necessary differ significantly for each of the materials. Therefore, each method is divergent in materials and steps. For these reasons the Inventions I-IV, VII-VIII are patentably distinct.

Furthermore, the distinct steps and products require separate and distinct searches. The inventions of Groups I-IV, VII-VIII have a separate status in the art as shown by their different classifications. As such, it would be burdensome to search the inventions of Groups I-IV, VII-VIII together.

9. Inventions V & VI and I & III / II & IV are related as product and process of use, respectively. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the products can be used to purify the protein to which the products bind or can be used to recombinantly express a protein.

Searching the inventions of Groups V & VI and I & III / II & IV together would impose serious search burden. The inventions of Groups V & VI and I & III / II & IV have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the methods of using the protein and polynucleotides and the polypeptides and polynucleotide are not coextensive. Prior art which teaches a polypeptide or polynucleotide would not necessarily be applicable to the method of using polypeptide or polynucleotide. Moreover, even if the products were known, the method of using the product may be novel and unobvious in view of the preamble or active steps.

10. Inventions V and VI and VII and VIII are unrelated because the product of groups V and VI are not used or otherwise involved in the process of group VII or VIII.

11. The inventions of Groups I- VIII have a separate status in the art as shown by their different classifications. As such, it would be burdensome to search any combination of the inventions of Groups I-VIII together.

12. Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the search required for each group is not required for the other groups because each group requires a different non-patent literature search due to each group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

13. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found

allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does

not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

14. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

15. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H. Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher Yaen, Examiner
Art Unit 1643
March 31, 2006

CHRISTOPHER YAEN
PATENT EXAMINER